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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,953	01/31/2006	Claes Gustafsson	11548-002-999	5350

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EXAMINER	
ZHOU, SHUBO	
ART UNIT	PAPER NUMBER
1631	
MAIL DATE	DELIVERY MODE
06/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,953	GUSTAFSSON ET AL.	
	Examiner	Art Unit	
	SHUBO (Joe) ZHOU	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,117-126,129,133-136,138,140,141,147,148,150-163 and 170-178* is/are pending in the application.

4a) Of the above claim(s) *138,141,151 and 176-178* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,117-126,129,133-136,138,140,141,147,148,150-163 and 170-175* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/31/06,3/10/06,2/16/07,8/11/08,10/14/09*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Election/Amendments/Status of the Claims

Applicant's elections of Group I and species 1A, 2B, and 3B in the responses filed 3/17/10 and 10/19/09, respectively, are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the elections have been treated as elections without traverse (MPEP § 818.03(a)).

Applicant's amendment to the claims filed 3/17/10 is also acknowledged and entered.

Claims 2-116, 127-128, 130-132, 137, 139, 142-146, 149, and 164-169 are canceled in the amendment.

Claims 1, 117-126, 129, 133-136, 138, 140-141, 147-148, 150-163, and 170-178 are thus pending.

Claims 138, 141, and 151 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Since newly added claims 176-178 are dependent from claim 17, a claim that had been canceled in the preliminary amendment filed 3/22/07 and not within the claim groupings listed in the restriction requirements mailed 7/27/09 and 1/4/10, they are also withdrawn from consideration as being drawn to nonelected invention.

Elections were made **without** traverse in the replies filed on 10/19/09 and 3/17/10.

Claims 1, 117-126, 129, 133-136, 138, 140-141, 147-148, 150-163, and 170-175

are presently under consideration.

Sequence Rules Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because the examiner was unable to find a paper copy of the Sequence Listing containing this sequences, and a statement under 37 CFR 1.821(f). Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to comply with these requirements may result in ABANDONMENT of the application under 37 CFR 1.821(g).

Specification

The specification is objected to because of the following including informalities:

Trademarks are used in this application, such as GENBANK™ on page 126. All trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort should be made to prevent their use in any manner that might adversely affect their validity as trademarks.

It appears that the last sentence bridging pages 74 and 75 is not grammatically proper. Furthermore, line 2 of page 75 refers to "Equation 4 below," but the equation therebelow is "Eq.6," not Equation 4.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 117-126, 129, 133-136, 138, 140-141, 147-148, 150-163, and 170-175 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is based on the court's decision in *In re Bilski*, and on the Office's recent "Interim Examination Instructions for Evaluating Subject Matter Eligibility Under 35 USC 101," effective August 24, 2009, which is available at the Office's website at http://www.uspto.gov/web/offices/pac/dapp/opla/2009-08-25_interim_101_instructions.pdf.

The instant claims are drawn to a method for constructing a variant set for modifying a biopolymer of interest, the method comprising: a) identifying a plurality of positions in said biopolymer of interest and, for each respective position in said plurality of positions, one or more substitutions for the respective position, wherein the plurality of positions and the one or more substitutions for each respective position in the plurality of positions collectively define a biopolymer sequence space; b) selecting a first plurality of variants of the biopolymer of interest thereby forming a variant set, wherein said variant set comprises a subset of said biopolymer sequence space; c) measuring a property of all or a portion of the variants in the variant set; and d) modeling a sequence-activity relationship between (i) one or more substitutions at one or more positions of the

biopolymer of interest represented by the variant set and (ii) the property measured for all or the portion of the variants in the variant set, wherein the sequence-activity relationship has a particular form and the modeling comprises particular steps as specified in the claims, e.g. claim 1.

As set forth in the Interim Examination Instructions (pages 4-5), a process claim, to be statutory under 35 USC 101, must pass the machine-or-transformation test (M-or-T test), that is, a claimed process must:

(1) be tied to a particular machine or apparatus; or

(2) particularly transform a particular article to a different state or thing.

In the instant case, the claimed process is not tied to a particular machine or a particular apparatus. As a matter of fact, there doesn't appear to be any machine tied to the claimed process. Furthermore, there is no physical transformation recited and achieved by the claimed process as it merely manipulates data. Note that while the claims recite "measuring a property of all or a portion of the variants," such a measuring step does not necessarily involve physical activity and achieve a physical transformation.

The rejection could be overcome by amendment of the claims to be tied to a particular machine or to recite and achieve a physical transformation by the method steps. Applicant, however, is cautioned against introducing new matter into the claims.

Applicant is also reminded that the court has pointed out that the involvement of the particular machine/apparatus or transformation in a claimed process must not merely be an insignificant extra-solution activity. See Flook, 437 U.S. at 590. Preambles, data-gathering and/or outputting result steps may fall within the category of such insignificant extra-solution activity.

As to claim 174, it is drawn to a "computer program product encoding instructions for implementing the method according to claim 1." Since one embodiment of the claimed invention could be simply a computer program or algorithm. A computer program, per se, i.e. the software, without being on a computer readable medium is nonstatutory. See MPEP 2106 IV (B) (1).

Claim Rejections-35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 117-126, 129, 133-136, 138, 140-141, 147-148, 150-163, and 170-175 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 and its dependent claims are amended to recite a form of Y=f(w1x1, w2x2 …. wixi), where xi is a descriptor of a substitution, a combination of substitutions, or a principal component of one or more substitutions ...." (Emphasis is added by the examine.) While it is noted that the original claim 52, now canceled, recites the same "form," but xi is defined therein as "a descriptor of a substitution, a combination of substitutions, or a component of one or more substitutions ...." Applicant also points to page 12 of the specification for support, but a review of the specification as a whole and

page 12 in particular again only reveals that xi is defined as "a descriptor of a substitution, a combination of substitutions, or a component of one or more substitutions ...." Thus, that xi is defined as "a principal component" among other things, is introduced new matter.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER